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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,096	09/26/2000	Linda S. Mansfield	MSU 4.1-526	7494

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MCLEOD & MOYNE
2190 COMMONS PARKWAY
OKEMOS, MI 48864

EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	4

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Copy

Office Action Summary	Application N .	Applicant(s)	
	09/670,096	MANSFIELD ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's preliminary amendment filed on 9/26/01 (Paper # 3) is acknowledged. Claims 4-20, 23-50 have been canceled. Claims 1-3, 21 and 22 are pending in the application.

Priority

2. This application is filed as a divisional application of co-pending application 09/513,086, which claims priority to Provisional Application 60/152,193 on 9/2/1999.

Information Disclosure Statement

3. The information disclosure statement filed 9/26/01 (Paper # 2) is acknowledged and a signed copy is attached to this Office Action.

Specification - Informalities

4. Applicant is advised to delete lines 5-10 on page 1 of specification since the invention is not sponsored by Federal agency. The specification page 11, line 3, states "the present invention will become increasingly apparent by reference to the following embodiments and drawings". However, no drawings have been filed with the application. Therefore, applicant is advised to correct the specification. Applicant is advised to correct any other errors that applicant may become aware of in the application.

Claim Rejections - 35 USC 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;

Claims1 and 21 are vague and unclear in the recitation of "antibodies which are against at least one epitope of a unique 16(±4) or 30(±4) antigen of Sarcocystis neurona". Does this mean antibodies bind to at least one epitope of a unique 16(±4) kD or 30(±4) kD antigen of *Sarcocystis neurona*"? For the purposes of examination, the claims will be treated as if the numbers are referring to molecular weights. It is also not clear whether "(±4) is intended to be a limitation of the claim. Applicant is advised to remove the parenthesis.

Claim 1 is vague and indefinite for the recitation of "at least one epitope of a unique 16(±4) or 30(±4)" antigens of Sacocysitis neurona because it is not clear what modifications or alterations have been made to these antigens to be unique? Applicant is advised to amend the claims to identify or describe or characterize the unique 16(±4) or 30(±4)" antigens of Sacocysitis neurona.

Claim 1 is vague in the recitation of "a vaccine for providing passive immunity to *S.neurona* infection". Generally vaccines are given to protect individuals from infections. Therefore, applicant is advised to amend the claim to recite "a vaccine for providing passive protection to an individual infected with S.neurona" or a vaccine for providing passive protection against S.neurona infection in an individual."

Claims 1 and 21 are vague and indefinite because the claims fail to satisfy the statute's requirement of adequately describing and setting forth the inventive concept. The claim does not sufficiently characterize the antibodies. If these antibodies bind to an unique epitope of an

antigen, then the claims should recite the specific amino acid sequences-or sequence identifier numbers of the antigen.

Claim 21 is vague in reciting "inoculating the equid." Does applicant intend to mean inoculating the equid with antibodies?

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims1-3, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition antibodies, does not reasonably provide enablement for a vaccine and a method for providing passive immunity to S.neurona infection in an equid comprising antibodies which are against at least one epitope of a unique 16(±4) or 30(±4) antigen of Sarcocystis neurona. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a vaccine and a method for providing passive immunity to S.neurona infection in an equid comprising antibodies which are against at least one epitope of a unique 16(±4) or 30(±4) antigen of Sarcocystis neurona.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the disclosed invention is a vaccine and a method for providing passive protective immunity to S.neurona infection in an equid comprising antibodies which are against at least one epitope of a unique 16(±4) or 30(±4) antigen of Sarcocystis neurona. The method for providing passive immunity thus requiring an *in vivo* enablement for intended use of the antibodies (i.e., pharmaceutical or therapeutic, page 15 of specification). Pharmaceutical uses include the *in vivo* diagnosis, prevention, treatment, or cure of a disease or condition. The specification discloses that the antibodies of the instant claims are intended for use as "pharmaceutical /therapeutic compositions" useful for treating/preventing S.neurona infection in an equid. The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo* uses of the claimed antibodies. The treatment /prevention of S.neurona infection in an equid with antibodies is highly complex and unpredictable. As taught by the prior art, Liang et al 1998 (Infection and Immunity; 66 (5) 1834-1838) it is apparent that not all antibodies generated to an antigen will neutralize the protein. Further, Liang *et al.* teach that '[A] although S. neurona was sensitive to specific antibodies, a 10-min exposure to antiserum was required to yield a significant reduction in parasite production. This may partially explain why protective antibodies to some apicomplexan parasites are effective *in vitro* but not *in vivo*. Newly released parasites are exposed to serum for a shorter time *in vivo*, and the access of neutralization-sensitive epitopes to antibody may be limited' (page 1837, right column, 3rd paragraph). Further, Liang *et al.* teach that cytotoxic T-cells are ineffective in attacking merozoites migrating to the central nervous system, and conclude while Sn 16 kD and Sn 14 kD

antigens are expressed *in vivo,* further investigation of these candidate antigens is necessary for inclusion in a vaccine (page 1837, bridging paragraphs of first and second columns). The results of and conclusion by Liang *et al.* clearly indicates that *in vitro* data does not necessarily correlate to or be extendable to *in vivo.* Whether the claimed vaccine prevents infection in an equine or prevents the spread of S. neurona to the nervous system and CSF is not known and needs to be experimented. The specification does not provide evidence that the vaccine (passive immunization with antibodies) either prevents the equid from infection or prevents the spread of *S. neurona* to the nervous system and CSF, which support such an assertion. Furthermore, it is unclear whether such an immunotherapy can be used to treat an ongoing infection or whether it is effective only in terms of prevention. The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). In light of the teachings of Liang *et al* that the ability of an antibody to function *in vitro* does not correlate to function *in vivo,* the instant specification has not given the necessary teaching to provide a nexus between the proposed antibody and a functional prophylactic vaccine. In addition, the specific antibodies which bind to an unique epitope of 16kD or 30 kD required to practice the claimed invention are not disclosed in the instant specification, nor the art of record. The high degree of unpredictability associated with the claimed method underscores the need to provide teachings in the specification that would provide the artisan with specific treatment regimens that achieve a therapeutic benefit; however, the specification does not provide such guidance and fails to provide the necessary guidance. Further, as indicated by Liang *et al.*, one cannot predict the activity of an antigen for use in a vaccine from *in vitro* data. While the immunological data of record strongly suggests that the antigens are cell surface antigens, there is no function ascribe to these antigens and thus, no nexus between immunization of animals with antibodies to the claimed antigens and targeting these antigens and disrupting any activity which would result in

protective prophylactic effect required of a vaccine. Without necessary specific guidance in the specification and the lack of correlative working examples, the claims would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan.

Status of Claims

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

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